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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/650,252  | 08/27/2003  | Zheng J. Li          | PC11724H            | 7177             |
| 28523   | 7590        | 05/18/2005           | EXAMINER            |                  |
| PFIZER INC.<br>PATENT DEPARTMENT, MS8260-1611<br>EASTERN POINT ROAD<br>GROTON, CT 06340 |             |                      | PESELEV, ELLI       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1623                |                  |

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/650,252             | LI ET AL.           |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Elli Peselev           | 1623                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 85-93 and 123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85-87,90,91 and 123 is/are rejected.
- 7) ☒ Claim(s) 88,89,92 and 93 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

*PD*

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Upon further consideration and search, the Final Rejection of October 22, 2004 is hereby withdrawn in order to introduce a new ground of rejection.

Claims 92 and 93 are objected to because of the following informalities: the term "azithromycin" (claim 92, line 3 and claim 93, line 2) is misspelled. Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 85-87, 91 and 123 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bosch et al (U.S. Patent No. 6,420,537).

The instant claims are directed to a mixture of azithromycin dihydrate and azithromycin solvate which contain ethanol, butanol, isopropanol or acetone.

Bosch et al a composition containing azithromycin of formula I and solvent (column 6, lines 64-67). Bosch et al further disclose that azithromycin can be in the form of dihydrate (column 6, lines 20-21) and the solvent can be ethanol, butanol, isopropanol or acetone (column 6, lines 37-41). The claimed mixture of azithromycin dihydrate and azithromycin solvate is seen to be inherently present in the composition disclosed by Bosch et al.

Claims 85 and 123 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aronhime et al (U.S. Patent No. 6,586,576).

Aronhime et al disclose precipitation of azithromycin dihydrate from acetone and water (column 3, lines 9-22).

The claimed mixture of azithromycin and acetone is seen to have been inherently formed from a mixture disclosed by Aronhime et al.

Claims 85 and 123 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bayod Jasanada et al (U.S. Patent No. 6,451,990).

Bayod Jasanada et al disclose recrystallization of azithromycin dihydrate from acetone or acetonitrile (table in columns 3-4). The claimed composition of azithromycin dihydrate and azithromycin solvate with acetone or acetonitrile is seen to have been inherently formed from such recrystallization solutions.

Claims 85-87 and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al (U.S. Patent No. 6,365,574) in combination with Bayod Jasanada et al (U.S. Patent No. 6,451,990).

Singer et al disclose ethanol solvate of azithromycin but do not disclose said solvent in combination with azithromycin dihydrate. However, since azithromycin dihydrate was well known in the art at the time the instant invention was made, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to combine ethanol solvate of azithromycin disclosed by Singer et al with azithromycin dihydrate disclosed by Bayod Jasanada et al because such a person would have expected the resulting composition to possess antibacterial activity.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 85, 86 and 90 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,861,413 in view of Bayod Jasanada et al (U.S. Patent No. 6,451,990). The claims of the U.S. Patent No. 6,861,413 are directed to a composition comprising n-propanol solvate of azithromycin but not to a mixture of azithromycin dihydrate and n-propanol solvate of azithromycin. However, since azithromycin dihydrate is well known in the art as disclosed by Bayod Jasanada et al and would be expected to possess the same activity as n-propanol solvate of azithromycin, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to combine azithromycin dihydrate with n-propanol solvate or azithromycin because such a person would have expected the resulting composition to possess antibacterial activity. .

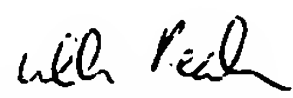
Claims 88, 89, 92 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

  
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